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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/852,919	05/10/2001	Qingsheng Zhu	279.330US1	4736
21186	7590	01/29/2004		
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402			EXAMINER OROPEZA, FRANCES P	
			ART UNIT 3762	PAPER NUMBER 12
DATE MAILED: 01/29/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/852,919

Applicant(s)

ZHU ET AL. *cd*

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/5/03 (Amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 21-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Amendments/ Arguments

1. Based on the amendments and response file 12/5/03, the Applicant's arguments are convincing and/or the amendments have overcome the rejections of record, hence the rejections of record are withdrawn and a new grounds of rejection established in the subsequent paragraphs.

Claim Rejections - 35 USC § 112

2. Claims 1-8, 10-14, and 16-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regard as the invention.

Claims 1 and 10 of generating the electric field in association with an atrial or ventricular depolarization appears to be in conflict with claims 5 and 18 and of generating the electrical field after heart depolarization.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chekanov (US 6201991) and in view of Hauck (US 6560489).

Chekanov discloses a method of prevention and treatment of atherosclerosis in the coronary blood vessels and teaches the use of a pulse generator (25) that includes therapy circuits and a system that includes one or two leads to create non-excitatory electrical field to prevent plaque build-up (col. 2 @ 13-34; col. 3 @ 42-49; col. 9 @ 10-13). The

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electrical field created in the coronary artery region by the two leads is read to impact the anterior vein, the lateral vein, the left marginal artery and the anterior interventricular artery (claim 15).

Chekanov et al. disclose the claimed invention except generating the electrical field during a refractory period at a higher strength and generating the electrical field during a non-refractory period at a lower strength (claim 9), delivering sub-stimulation pulses in association with atrial or ventricular depolarization (claims 1, 10, 15, 20), sensing heart rhythms (claim 4), and delivering stimulation during and after the depolarization (claim 5 and 18).

As to claim 9, Hauck teaches cardiac treatment using subthreshold electrical current to generate an electrical field during a refractory period at a higher strength and generate the electrical field during a non-refractory period at a lower strength (col. 4 @ 19-37) for the purpose of providing therapeutic subthreshold electrical fields that avoid inducing depolarization of the cardiac tissue, resulting in an unwanted cardiac contraction.

As to claims 1, 10, 15 and 20, Hauck teaches sub-threshold stimulation is delivered in association with a ventricular or atrial depolarization (figure 3; col. 4 @ 34-36; col. 5 @ 34-39) to produce an electrical field that does not interfere with the heart rhythm, hence producing an electrical field during a refractory period of the heart for the purpose of providing therapeutic subthreshold electrical fields that avoid inducing depolarization of the cardiac tissue, resulting in an unwanted cardiac contraction.

As to claims 4, 5, and 18, the timing of the stimulation to produce the electrical field is regulated by sensing the heart rhythm (col. 4 @ 19-21) and the strength of the

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stimulation creating the resultant strength of the electric field is regulated by measuring the electric field strength such that that simulation is delivered at a subthreshold level. The stimulation is provided at various points in the cardiac cycle with an appropriate strength, either during or following the depolarization (col. 4 @ 19-50), for the purpose of providing therapeutic subthreshold electrical fields that avoid inducing depolarization of the cardiac tissue, resulting in an unwanted cardiac contraction.

It would have been obvious to one having ordinary skill in the art at the time of the invention to have used subthreshold electrical current that generates an electrical field during a refractory period at a higher strength and generate the electrical field during a non-refractory period at a lower strength, delivering sub-stimulation pulses in association with atrial or ventricular depolarization, sensing heart rhythms, and delivering the stimulation during and after the depolarization in the Chekanov system in order to avoid the treatment pulse inducing a life threatening cardiac arrhythmia, placing the patient in grave danger (abstract; col. 1 @ 18-21; col. 2 @ 35-53; col. 3 @ 25 – col. 4 @ 61).

4. Claims 1-8 and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chekanov (US 6201991) in view of Hauck (US 6560489) and further in view of Dev et al. (US 6347247).

As discussed in paragraph 3 of this action, modified Chekanov discloses the claimed invention except for:

- the lead including an electrode patch (claims 2 and 12),
- spacing the electrical fields about 10 seconds apart (claims 6 and 17), and
- the lead having two electrodes (claims 7 and 14).

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Dev et al. disclose a device to dilate vessels using electrical fields to prevent plaque build-up (col. 2 @ 47-51; col. 6 @ 21-27) and teach that it is known: 1) to apply the method to the coronary artery, using an exo-luminal electrode (known in the cardiac art as related to the heart to optionally be an electrode patch) to establish the electrical field, 2) to space the electrical fields about 10 seconds apart, and 3) to provide two electrodes. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the modified method of prevention and treatment of atherosclerosis in a blood vessel as taught by modified Chekanov, with the following elements as taught by Dev et al.:

- the lead including an electrode patch (claims 2 and 12) read as exo-luminal placement of the electrode in the heart for treatment of the coronary artery (col. 6 @ 28-35) to provide an electrode that enable creation of a broad electrical field enabling treatments of large areas of cardiac tissue,
- spacing the electrical fields about 10 seconds apart (claims 6 and 17) (c 7 @ 45-46) where one second or longer is read as about 10 seconds, to have a pulse timing sequence that is effective in treating plaque build-up, and
- the lead having two electrodes (claims 7 and 14) (col. 8 @ 59-64) to enable versatility in the creation of the electrical field.

As to generating the electrical field including outputting a non-excitatory electrical field, Chekanov discloses an implantable generator (figure 1 – (26); col. 2 @ 25-28) generating an electrical field (col. 1 @ 3 @ 42-49). The Applicant's specification teaches a non-excitatory electric field in the range 30 to 60 pulses per minute (page 7,

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line 23) and Chekanov teaches stimulation in the range of 30 to 120 beats per minute (col. 2 @ 66-67).

As to clarification about vessel dilation using electrical fields to prevent plaque build-up, Dev et al. teach increasing the flow of fluid through a vessel by applying an electrical impulse (col. 2 @ 46-51), the impulse creating an electric field to induce vasodilation (col. 3 @ 15-22). Plaque can be removed/ denuded as part of the treatment process (col. 2 @ 61-65; col. 6 @ 42-61), hence removing/ reducing the size of the site for plaque agglomeration and ultimately preventing/ reducing plaque build-up.

Other Prior Art Cited

5. The prior art made of record and not relied upon is considered pertinent to the Applicant's disclosure. US 6666863 to Wentzel et al. teaches myocardial revascularization and waveform timing (col. 2 @ 49-62).

Statutory Basis

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza whose telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

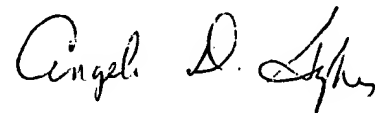
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If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communication and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
1/20/04



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